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EXAMINER

NATNITHITHADHA, NAVIN

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/509,019

Applicant(s)

KUBO, TAKESHI

Examiner

Navin Natnithithadha

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 9, 10, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) 4, 8 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>09272004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 1-13 have been amended. Claims 1-13 are pending.
2. The Abstract has been amended. Figure 14 of the Drawings has been amended.

### ***Drawings***

3. The drawings were received on 22 November 2004. These drawings are acceptable.

### ***Claim Objections***

4. Claims 1, 2, 5-8, and 13 are objected to because of the following informalities:

In claim 1 line 11, claim 2 line 10, claim 5 line 3, claim 6 line 4, claim 7 line 4, claim 8 lines 6-10, and claim 13, lines 7-8, "estimated mean arterial pressure" needs to be amended to - - said mean blood pressure - - in order to provide proper antecedent basis for the term. Appropriate correction is required.

5. Claims 1 and 13 are objected to because of the following informalities:

In the preamble of claim 1, the Examiner suggests including "a cuff adapted for attachment to a subject and pressurized and depressurized to measure said subject's blood pressure" in the body of the claim as the first element in the apparatus in order to properly describe the structure of the apparatus.

In the preamble of claim 13, the Examiner suggests including "employing an electronic blood pressure monitor having a cuff attached to a subject and pressurized and depressurized in order to measure the subject's blood pressure" in the body of the claim as the first step in the method in order to properly describe the steps of the method. In addition to the preamble of claim 13, the Examiner suggests amending "A blood pressure measurement method" to - - A method of measuring blood pressure - -. Appropriate correction is required.

6. Claim 2 is objected to because of the following informalities:

In line 2, "includes" should be amended to - - comprises - - in order to have consistent language throughout the claim. Line 4 should be amended to - - a pulse wave detected; - - and new line should begin with "said diastolic blood pressure detector comprises..." in order to show a separation in the limitation for the pulse wave detector and the diastolic blood pressure detector. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

7. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Support for claim 8 can be found on page 13, lines 1-24, of the Specification. However, it is not clear from the Specification what the Applicant means by "this is discarded" in the claim. Based on the claim, it appears that "this is discarded" refers to the "estimated mean arterial pressure" is discarded, and the flat amplitude proceeds to

Art Unit: 3736

determine the systolic blood pressure by an alternate estimate of mean arterial pressure. But, if this is the case, the Specification does not provide sufficient support for this function of the flat amplitude detector. The Examiner suggests using language consistent with what is disclosed the Specification. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 5 (5/2), 6 (6/2), 7 (7/2), and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Nishibayashi, US 6,589,186 B2.

Claim 1: Nishibayashi teaches an "electronic blood pressure monitor" (blood pressure measuring apparatus) 10 (see fig. 2) having a cuff 12 "adapted for attachment to a subject and pressurized and depressurized" (see col. 3, lines 49-67) to "measure said subject's blood pressure" (see col. 1, lines 43-53), comprising:

a "pulse wave detector" (pulse wave filter circuit or cuff pulse wave detecting device) 26 "detecting said subject's pulse wave as said cuff occludes said subject" (see fig. 2 and col. 4, lines 1-21);

Art Unit: 3736

a "mean blood pressure estimator" (mean-blood-pressure determining means) 56 "estimating said subject's mean blood pressure from said pulse wave detected by said pulse wave detector" (see fig. 2 and col. 5, line 54 to col. 6, line 2);

a "diastolic blood pressure detector" (diastolic-blood-pressure determining means) 54 "detecting said subject's diastolic blood pressure" (see fig. 2 and col. 5, lines 34-53); and

a "systolic blood pressure calculator" (systolic-blood-pressure determining means) 60 "calculating said subject's systolic blood pressure from said estimated mean arterial pressure, said detected diastolic blood pressure and a waveform of said pulse" (see fig. 2 and col. 6, lines 34-64).

Claim 2: Nishibayashi teaches the pulse wave detector 26 comprises a "waveform parameter calculator" (pulse-wave-magnitude determining means) 58 "calculating a wave form parameter indicative of a feature of a waveform of a pulse detected" (minimal magnitude,  $I_{min}$ , a mean magnitude,  $I_g$ , and a maximal magnitude,  $I_{max}$ , of the cuff pules wave CW) (see col. 6, lines 3-33); the diastolic blood pressure detector 54 comprises a "diastolic blood pressure calculator" (oscillometric algorithm) "using said waveform parameter to calculate diastolic blood pressure" (determines an envelope of respective amplitudes,  $A$ , of respective heartbeat-synchronous pulses of the cuff pulse wave CW, determines a differentiated waveform or curve of the thus determined envelope, and determines as the diastolic blood-pressure value  $BP(DIA)$ , a cuff pressure  $P_c$  at a time when the differentiated curve shows an inflection point) (see col. 5, lines 36-53); the mean blood pressure estimator 56 "employs the waveform

Art Unit: 3736

parameter to determine a reference pressure point within any range from a point of no more than systolic blood pressure to a point no less than a diastolic blood pressure and with reference to said reference pressure point calculates estimated mean arterial pressure by using said waveform parameter correlated with an average value of an intra-arterial pressure waveform" (determines, according to the oscillometric algorithm, an envelope of respective amplitudes A of respective heartbeat synchronous pulses of the cuff pulse wave CW, and determines, as the mean blood-pressure value BP(MEAN), a cuff pressure Pc at a time when the envelope shows a peak, i.e., the greatest amplitude) (see col. 5, lines 54-66); and the systolic blood pressure calculator 60 "correlates said diastolic blood pressure and said estimated mean arterial pressure to said pulse waveform's maximum and average values and calculates a blood pressure corresponding to said pulse waveform's maximum value point to determine systolic blood pressure" (determines a systolic blood-pressure value BP(SYS) of a body portion of the patient on which the cuff 12 is worn, based on the diastolic and mean blood-pressure values BP(DIA), BP(MEAN) determined by the blood-pressure determining means 52 and the minimal, mean, and maximal pulse-wave magnitudes lmin, lg, lmax determined by the pulse-wave-magnitude determining means 58) (see col. 6, lines 35-64). The systolic-blood-pressure determining means 60 "correlates" by using a relationship L or using Expressions 1 and 2 (see col. 6, lines 45-64).

Claim 5 (5/2, claim 5 dependent on claim 2): Nishibayashi teaches the mean blood pressure estimator 56 "determines as said estimated mean arterial pressure a cuff pressure allowing a pulse wave amplitude to be maximized" (determines, as the mean

Art Unit: 3736

blood-pressure value BP(MEAN), a cuff pressure  $P_c$  at a time when the envelope shows a peak, i.e., the greatest amplitude) (see col. 5, lines 54-66).

Claim 6 (6/2): Nishibayashi teaches the mean blood pressure estimator 56 “uses an area of an apical portion of a pulse wave amplitude envelope to perform an operation to determine said estimated mean arterial pressure” (the mean, i.e., area-gravity-center magnitude  $I_g$  may be determined by summarizing a waveform of the one heartbeat-synchronous pulse of the cuff pulse wave CW and dividing the thus summarized value by a period, T, of the one pulse) (see fig. 4 and col. 6, lines 3-24).

Claim 7 (7/2): Nishibayashi teaches the mean blood pressure estimator 56 “uses a waveform parameter indicative of stiffness in a vicinity of a pulse wave rising point to determine said estimated mean arterial pressure” (determines, as a mean blood-pressure value BP(MEAN) of the patient, a cuff pressure  $P_c$  at a time(i.e., a time,  $t_3$ , shown in FIG. 3) when the greatest amplitude A is shown on the envelope) (see col. 8, lines 35-38).

Claim 13: Nishibayashi teaches a blood pressure measurement method employing an “electronic blood pressure monitor” (blood pressure measuring apparatus) 10 (see fig. 2) having a cuff 12 “attached to a subject and pressurized and depressurized” (see col. 3, lines 49-67) in order to “measure the subject’s blood pressure” (see col. 1, lines 43-53), comprising:

“detecting a pulse wave of the subject occluded by said cuff” (function of pulse wave filter circuit or cuff pulse wave detecting device 26) (col. 4, lines 1-21);



"estimating the subject's mean blood pressure from a pulse wave detected"  
(function of mean-blood-pressure determining means 56) (see col. 5, line 54 to col. 6,  
line 2);

"detecting the subject's diastolic blood pressure" (function diastolic-blood-  
pressure determining means 54) (see col. 5, lines 34-53); and

"calculating the subject's systolic blood pressure from the estimated mean  
arterial pressure, the detected diastolic blood pressure and the detected pulse wave's  
waveform" (function of systolic-blood-pressure determining means 60) (see col. 6, lines  
34-64).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all  
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 9 (9/2) and 10 (10/2) are rejected under 35 U.S.C. 103(a) as being  
unpatentable over Nishibayashi, US 6,589,186 B2, as applied to claim 2 above, and  
further in view of Oka et al, US 5,836,887 A.

Claims 9 (9/2) and 10 (10/2): Nishibayashi does not teach "said systolic blood  
pressure calculator calculates systolic blood pressure for each pulse wave of a plurality  
of pulses obtained during measurement and provides an average of such obtained  
systolic blood pressures as an ultimate systolic blood pressure" and "a pulse wave

Art Unit: 3736

average calculator calculating average values of a plurality of pulse waves, respectively, from said average values calculated by said pulse wave average calculator, and determines an average of these calculated systolic blood pressures as an ultimate systolic blood pressure". However, these functions are merely computations, i.e. averaging, of data, in which the systolic blood pressure determining means 60 is capable of performing. In addition, averaging systolic blood pressure is well-known in the art. For example, Oka teaches a moving average calculating means 80 calculating a plurality of moving averages ( $P_{AV1}$  and  $P_{AV2}$ ) for a plurality of systolic blood pressure values (see col. 5, lines 54-66, and col. 8, lines 32-40). Each moving average represents an "ultimate systolic blood pressure" relative to each time period. Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Nishibayashi to calculate a moving average of the systolic blood pressures calculated in order to determine the abnormality of the blood pressure as suggested by Oka (see col. 8, lines 32-53).

10. Claim 12 (12/2) is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishibayashi, US 6,589,186 B2, as applied to claim 2 above, and further in view of Takatsu et al, US 4,494,305 A.

Claim 12 (12/2): Nishibayashi teaches a display device 40. Nishibayashi does not teach a "blood pressure variation range display calculating a systolic blood pressure for each pulse wave of a plurality of pulses obtained during measurement, and displaying how a plurality of systolic blood pressures vary in value". However, it is well known in

Art Unit: 3736

the art at the time the invention was made to have a display capable of calculating blood pressure values for each pulse wave of a plurality of pulses obtained during measurement and displaying how plurality of blood pressure values vary. For example, Takatsu teaches a display matrix 46 (see fig. 6) including a first display portion 47 for indicating by digits a maximum blood pressure 47a, an average blood pressure 47b and a minimum blood pressure 47c determined at each measuring cycle (pulse wave cycle) (see col. 4, lines 37-50). The display matrix 46 also includes a second display portion 48 for indicating the blood pressure time-wise varying trends in a two-dimensional table 49 defined by an x axis 49a indicative of time and a y axis 49b indicative of blood pressure. Therefore, it would have been obvious for one of ordinary skill in the art to modify Nishibayashi's display device 40 to incorporate Takatsu's display matrix 46 in order to show a trend analysis of the systolic blood pressures calculated by Nishibayashi.

11. Claims 3, 5 (5/2), 6 (6/2), and 7 (7/2) are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishibayashi, US 6,589,186 B2, as applied to claim 2 above, and further in view of Miyazaki, US 5,868,679 A.

Claim 3: Nishibayashi teaches a pulse-wave filter circuit 26. Nishibayashi is silent on the function of the filter 26. Additionally, Nishibayashi does not teach a "waveform distortion corrector correcting said waveform parameter to cancel an error introduced by a distortion of a detected pulse wave relative to said arterial waveform into systolic blood pressure calculated." However, Miyazaki teaches a similar device (same

Art Unit: 3736

Assignee, Colin Corporation) comprising a band-pass filter, i.e. "waveform corrector", 22, which permits only a 1 to 10 Hz frequency band component to produce a pulse-wave signal SM1, which is free from noise such as motion-induced artifact noise.

Therefore, Miyazaki's filter 22 would "correct" the distortion of the waveform due to motion-induced artifact noise in the detected pulse wave signal (from a pulse wave detector) relative to the actual arterial waveform. Thus, it would have been obvious for one of ordinary skill in the art to modify Nishibayashi's filter with Miyazaki's filter in order to have a noise free pulse waveform for further processing.

Claims 5 (5/3), 6 (6/3), and 7 (7/3): The subject matter of claims 5-7 were anticipated by Nishibayashi as discussed above (see section # 8 above).

12. Claims 9 (9/3) and 10 (10/3) are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishibayashi, US 6,589,186 B2, in view of Miyazaki, US 5,868,679 A, as applied to claim 3 above, and further in view of Oka et al, US 5,836,887 A.

Claims 9 (9/2) and 10 (10/2): The subject matter of claims 9 and 10 were unpatentable over Nishibayashi in view of Oka as discussed above (see section # 9 above).

13. Claim 12 (12/3) is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishibayashi, US 6,589,186 B2, in view of Miyazaki, US 5,868,679 A, as applied to claim 3 above, and further in view of Takatsu et al, US 4,494,305 A.

Claims 9 (9/3) and 10 (10/3): The subject matter of claims 9 and 10 were unpatentable over Nishibayashi in view of Takatsu as discussed above (see section # 10 above).

***Allowable Subject Matter***

14. Claims 4, 8, and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Claim 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

16. The following is a statement of reasons for the indication of allowable subject matter:

Claim 4 (5/4, 6/4, 7/4, 8/4, 9/4, 10/4, 11/4, 12/4): The prior art of record does not teach the electronic blood pressure monitor of claim 3, including: a waveform distortion corrector makes a correction based on a waveform parameter representative of a relationship between intra-arterial pressure and vascular volume obtained when the cuff effects occlusion.

Claim 8 (8/2, 8/3): The prior art of record does not teach the electronic blood pressure monitor of claims 2, 3, or 4, including: a flat-amplitude detector detecting when there exists a cuff pressure range free of significant variation in pulse wave amplitude when said cuff pressure is changed (i.e. a flat portion of the curve in Figure 10 of the

Art Unit: 3736

disclosure), wherein: when said flat amplitude detector detects that in a cuff pressure range free of significant variation in pulse wave amplitude (i.e. detects a flat portion) there exists estimated mean [blood] pressure corresponding to a maximized pulse wave amplitude, this is discarded; and systolic blood pressure is determined from one or both of the estimated mean [blood] pressure obtained by an operation based on an area of an apical portion of said pulse wave amplitude envelope and the estimated mean [blood] pressure obtained as based on a waveform parameter indicative of stiffness in a vicinity of a pulse wave rising point. Support for this claim is discussed on page 13, lines 1-24, of the Specification.

Claim 11 (11/2, 11/3): The prior art of record does not teach the electronic blood pressure monitor of claims 2, 3, or 4, including: the systolic blood pressure calculator calculates a systolic blood pressure for each pulse waveform of a plurality of pulses obtained during measurement, classifies such results into a plurality of classes within a range of cuff pressure being applied when a pulse wave is generated, and performs an operation weighting an average value of each class to determine a systolic blood pressure to be a result of the measurement.

### ***Conclusion***

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

Art Unit: 3736

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Navin Natnithithadha  
Patent Examiner  
GAU 3736  
08 August 2005